



UNITED STATES PATENT AND TRADEMARK OFFICE

UNITED STATES DEPARTMENT OF COMMERCE
United States Patent and Trademark Office
Address: COMMISSIONER FOR PATENTS
P.O. Box 1450
Alexandria, Virginia 22313-1450
www.uspto.gov

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/295,463	04/13/1999	LEX M. COWSERT	ISIS-3455	7206
35807	7590	12/09/2004	EXAMINER	
FENWICK & WEST LLP 801 CALIFORNIA STREET MOUNTAIN VIEW, CA 94014			MARSCHEL, ARDIN H	
			ART UNIT	PAPER NUMBER
			1631	

DATE MAILED: 12/09/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

Advisory Action

Application No.

09/295,463

Applicant(s)

COWSERT ET AL.

Examiner

Ardin Marschel

Art Unit

1631

--The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

THE REPLY FILED 13 September 2004 FAILS TO PLACE THIS APPLICATION IN CONDITION FOR ALLOWANCE. Therefore, further action by the applicant is required to avoid abandonment of this application. A proper reply to a final rejection under 37 CFR 1.113 may only be either: (1) a timely filed amendment which places the application in condition for allowance; (2) a timely filed Notice of Appeal (with appeal fee); or (3) a timely filed Request for Continued Examination (RCE) in compliance with 37 CFR 1.114.

PERIOD FOR REPLY [check either a) or b)]

- a) ☒ The period for reply expires 3 months from the mailing date of the final rejection.
- b) ☐ The period for reply expires on: (1) the mailing date of this Advisory Action, or (2) the date set forth in the final rejection, whichever is later. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of the final rejection. ONLY CHECK THIS BOX WHEN THE FIRST REPLY WAS FILED WITHIN TWO MONTHS OF THE FINAL REJECTION. See MPEP 706.07(f).

Extensions of time may be obtained under 37 CFR 1.136(a). The date on which the petition under 37 CFR 1.136(a) and the appropriate extension fee have been filed is the date for purposes of determining the period of extension and the corresponding amount of the fee. The appropriate extension fee under 37 CFR 1.17(a) is calculated from: (1) the expiration date of the shortened statutory period for reply originally set in the final Office action; or (2) as set forth in (b) above, if checked. Any reply received by the Office later than three months after the mailing date of the final rejection, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

1. ☐ A Notice of Appeal was filed on _____. Appellant's Brief must be filed within the period set forth in 37 CFR 1.192(a), or any extension thereof (37 CFR 1.191(d)), to avoid dismissal of the appeal.
2. ☒ The proposed amendment(s) will not be entered because:
- (a) ☒ they raise new issues that would require further consideration and/or search (see NOTE below);
 - (b) ☐ they raise the issue of new matter (see Note below);
 - (c) ☒ they are not deemed to place the application in better form for appeal by materially reducing or simplifying the issues for appeal; and/or
 - (d) ☐ they present additional claims without canceling a corresponding number of finally rejected claims.

NOTE: See further explanation as attached.

3. ☐ Applicant's reply has overcome the following rejection(s): _____.
4. ☐ Newly proposed or amended claim(s) _____ would be allowable if submitted in a separate, timely filed amendment canceling the non-allowable claim(s).
5. ☒ The a) ☐ affidavit, b) ☐ exhibit, or c) ☒ request for reconsideration has been considered but does NOT place the application in condition for allowance because: of reasons of record as explained further as attached.
6. ☐ The affidavit or exhibit will NOT be considered because it is not directed SOLELY to issues which were newly raised by the Examiner in the final rejection.
7. ☒ For purposes of Appeal, the proposed amendment(s) a) ☒ will not be entered or b) ☐ will be entered and an explanation of how the new or amended claims would be rejected is provided below or appended.

The status of the claim(s) is (or will be) as follows:

Claim(s) allowed: _____.

Claim(s) objected to: _____.

Claim(s) rejected: 55,56,58-72,74-87 and 99-102.

Claim(s) withdrawn from consideration: _____.

8. ☐ The drawing correction filed on _____ is a) ☐ approved or b) ☐ disapproved by the Examiner.
9. ☒ Note the attached Information Disclosure Statement(s) (PTO-1449) Paper No(s). (1 sheet).
10. ☒ Other: Ex. Int. Sum of 12/6/04

DETAILED ACTION

Further explanation of item # 2a) on the enclosed Advisory action:

Although not indicated as an amendment to the claims, applicants' claim set, filed 9/13/04, does, in fact, amend claim 55 via the inclusion of part designations a), b), and c) which were not present in the immediately earlier submitted form of claim 55.

Although of a formal nature, these amendments are still amendments to the claim and improper due to no indication of the claim status as (Currently amended). The (Previously Amended) status identifier of claim 55 is improper for two reasons. Firstly, 37 CFR 1.121 which provides status identifiers for claim amendments does not provide for an identifier of (Previously Amended). Secondly, the amending of claim 55 proposed on 9/13/04, should have been indicated by the identifier (Currently amended). This is a new issue that would require further consideration and/or search.

Further explanation of item # 5 on the enclosed Advisory action:

The rejection of claims 55, 56, 58-72, 74-87, and 99-102 based on NEW MATTER is maintained and reiterated from the previous office action, mailed 6/9/04.

Applicants firstly argue that written support is provided in Figure 1, step 300. Consideration of said step 300 in Figure 1 reveals none of the thermodynamic testing of instant claim 55 nor the other criteria are set forth therein thus making this citation non-persuasive.

Applicants secondly argue that written support is provided regarding the flow of data and materials amongst said step 300 in Figures 4 and 5. Consideration of said Figures 4 and 5 in the context of Figure 1 reveals the instant claim 55 thermodynamic testing with the other criteria are set forth therein is not what is set forth in said Figures 4 and 5. Rather, Figure 4, step 304 sets forth a generation of "all possible oligonucleotide sequences capable of hybridizing to target sequence" which is not what

Art Unit: 1631

claim 55 requires or is directed to. Also, Figure 4, step 306, calculates a "series" of thermodynamic, sequence, and homology scores, whereas, in contrast, no such scoring is seen in claim 55. A selection step regarding ranges is set forth in step 348 which also indicates that the Figure 4 methodology is different from that of instant claim 55 and thus making these citations clearly non-persuasive. Figure 5 sets forth steps 349 and 350 which firstly query desirability of functional regions selection followed by selection of functional sites(s) but without any indication that this is performed with thermodynamic property practice as in instant claim 55 per se. It is noted that one embodiment of these property selection practices of claim 55 is a thermodynamic property combined with only a functional regions targeting which is not seen as an option in Figures 4-5. Instead Figures 4-5 require a far more limited methodology such as in steps 304, 306, 347, 348, 349, 350, and 370 which are not optional selections within instant claim 55. The combination of thermodynamic property selection and functional site(s) targeting is not an option within Figure 4-5 and thus non-persuasive.

Applicants next argue that written support is provided on page 16, line 26, through page 21, line 26. This page 16-21 citation has already been summarized in the Final office action, mailed 6/9/04, and is reiterated here as equally non-persuasive. Applicants also refer to Figure 6. Consideration Figure 6 reveals a particular set of thermodynamic properties directed to various free energies, none of which are set forth in claim 55 nor is this thermodynamic property selection combined specifically with any of the "other criteria" listed in claim 55. Applicants then argue that Figure 5 explicitly teaches the "other criteria" of claim 55. Consideration of said Figure 5 has failed to reveal even one of such "other criteria" as present in now pending claim 55 thus making this argument non-persuasive.

Art Unit: 1631

Applicants further argue page 20, line 24, through page 22, line 2, but without any disclosure found therein for the combination of thermodynamic properties with the specific "other criteria" of instant claim 55 thus making this argument non-persuasive.

Applicants then argue that Figure 5, step 349, cites a decision point. This argument is non-persuasive as there is no such decision point in claim 55.

Applicants then argue that this decision point is followed by steps 350 and 370. It is acknowledged that step 350 is one of the "other criteria" in instant claim 55, but that this step still is not disclosed as being combined with thermodynamic properties without some type of decision step, 349 thus being different methodology from that of instant claim 55. Applicants' further arguments regarding "uniform distribution to target nucleic acid sequences" and "target accessibility" also suffer from the same lack of combination disclosure with thermodynamic properties per se without decision steps thus also failing to provide written basis for claim 55.

Applicants then argue that there is no "haec verba requirement" for newly added claim limitations and does not have to literally recite the wording of the claims. This is acknowledged, however, applicants have apparently arbitrarily picked and chosen unconnected limitations to assemble claim 55. Therefore, claim 55 lacks written support for such combination limitations as now claimed within claim 55. The written description requirement under 35 USC, first paragraph, at least requires written support for methods as claimed with at least the particulars of concept combinations of limitations being disclosed as filed to prevent a NEW MATTER rejection for newly amended claims.

The prior art rejection of claims 55, 56, 58-72, 74-87, and 99-102 based on the combination of references listed in the previous office action, mailed 6/9/04, is maintained and reiterated as not being argued further by applicants.

Art Unit: 1631

No claim is allowed.

Papers related to this application may be submitted to Technical Center 1600 by facsimile transmission. Papers should be faxed to Technical Center 1600 via the Central PTO Fax Center. The faxing of such papers must conform with the notices published in the Official Gazette, 1096 OG 30 (November 15, 1988), 1156 OG 61 (November 16, 1993), and 1157 OG 94 (December 28, 1993)(See 37 CFR § 1.6(d)). The Central PTO Fax Center number is (703) 872-9306.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Ardin Marschel, Ph.D., whose telephone number is (571) 272-0718. The examiner can normally be reached on Monday-Friday from 8 A.M. to 4 P.M.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Michael Woodward, Ph.D., can be reached on (571) 272-0722.

Any inquiry of a general nature or relating to the status of this application should be directed to Legal Instrument Examiner, Tina Plunkett, whose telephone number is (571) 272-0549.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

December 6, 2004


ARDIN H. MARSCHEL
PRIMARY EXAMINER 12/6/04